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VIA FEDERAL EXPRESS

Food and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, FL 32751

WARNING LETTER

FLA-02-13

November 7, 2001

FACILITY ID # 102012

Sharon Bakalo, Administrator  
Aventura Diagnostic Center  
2100 E Hallandale Beach Blvd  
Hallandale, Florida 33009

Dear Ms. Bakalo:

We are writing to you because on October 23, 2001, your facility was inspected by a representative of the State of FL, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility. Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection indicates that the finding or violation was cited during the previous inspection and there is therefore a repeat violation. A finding is considered a repeat finding if the same type of violation was cited during the previous inspection, whether or not the finding is associated with the same piece of equipment (x-ray unit, processor, darkroom) or the same personnel in any given category.

Level 2 – REPEAT: The time period between the previous and current surveys for the x-ray unit exceeds 14 months.

Also the facility was cited because there is no designated audit/reviewing-interpreting physician at the facility.

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).\*

Please submit your response to:

Timothy J. Couzins, Compliance Officer, U. S. Food and Drug Administration,  
555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov>.

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If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact D. Janneth Caycedo, Consumer Safety Officer, Boca Raton Resident Post, FDA, at 561-338-5236, ext. 23.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Emma R. Singleton". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Emma R. Singleton  
District Director, Florida District